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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,421	12/08/2003	Henry Nita	PAT-1540	2510

7590 01/09/2007
Raymond Sun
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Tustin, CA 92782

EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/730,421

Applicant(s)

NITA ET AL.

Examiner

Peter J. Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The action is non-final. RCE filed 12-6-06.

Claims 17-32 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-18, 20-21, 23, 25, 27 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer et al. (6,522,930) in view of Bacich et al. (5,389,100) or Kesten et al. (6,251,104).

Independent claim 17

Schaer discloses a method of placing the distal end of an ultrasound (col. 2:46-51) catheter at a desired location inside a vessel, comprising:

providing a sheath (124, figures 14-15) having an elongate body that has a lumen and a distal end;

providing a guidewire (col. 12:55-61);

extending the ultrasound (col. 2:46-51) catheter (130) over the guidewire (col. 12:55-61) through the lumen of the sheath (124); and

extending the sheath (124) through the lumen of a guide catheter (col. 4:20-31).

Schaer is silent regarding express disclosure of an angled sheath. Sheath element 124 in Schaer figure 14 appears straight. However, the relevant disclosure (col. 26:6-9) makes obvious that sheath element 124 may be shaped in a position that permits the element to be placed where needed. The suggested change in shape could include a distal end that is angled as now claimed by the Applicant. Kesten et al. (see figures 3-6) and Bacich et al. (figure 1 element 31 – also note col. 4:66 through col. 5:1) show sheaths with angled distal ends that could be seamlessly substituted for element 124 in figure 14 of Schaer.

Dependent claims (below numbers correspond to claims)

18. The method of claim 17, further including: advancing and retracting the sheath (124) independently beyond the distal end of the ultrasound catheter (130). These steps are depicted in time sequential figures 14 and 15.

20. The method of claim 17, further including: torquing (see double-sided arrow at the distal end of the sheath in figure 15) the sheath to redirect the angled distal end of the sheath.

21. The patented sheath (124) includes an outer polymeric material (multiple tubings, col. 25:52) with a reinforcing layer (laminated braided structure, col. 25:53-55).

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23. The distal shaft member (134, figure 15) has a smaller outer diameter than the main shaft member.

25. Excluding the porous membrane 132 in element 124 of figures 14 and 15, the drawings depict uniformity stingly inferring that 124 the distal shaft member 134 is of equal hardness to 124 (the main body of the sheath).

27. Element 124 (distal end, figure 15) is angled within the claimed dimensions.

Therefore, at the time of the invention **it would have been obvious** to one of ordinary skill in the art to modify Schaer et al. (6,522,930) in view of Kesten (6,251,104) or Bacich et al. (5,389,100) by designing a sheath with an angled distal end. The **motivation** would be permit proper placement of the sheath in the patient's body as suggested in Schaer (col. 26:6-9) and Bacich et al. (note col. 4:66 through col. 5:1).

2. Claims 19, 22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer et al. (6,522,930) in view of Kesten (6,251,104).

Schaer discloses:

19. The method of claim 17, further including: retracting the sheath (14) proximal from the distal end of the catheter (16). The same reversal rationale applies here. The patent discloses advancing and retracting the catheter relative to the sheath. *In re*

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Gazda (below) indicates these differences between the patent and the Applicant's claims as obvious.

Schaer is silent with respect to lubricious coatings.

Regarding claims 22 and 26, in an analogous device, Kesten discloses an elongate body (14/26; figure 2) with lubricious coatings. Lubricious coatings 27 and 30 both lie in inner surfaces of elements 14 and 13. According to MPEP 2144.04 VI. A., which is presented below, the reversal is obvious. Note also that the reversal here yields the same ends/result, to lubricate/facilitate movement of the two parts providing the motivation to combine the patents.

VI. REVERSAL, DUPLICATION, OR REARRANGEMENT OF PARTS

A. Reversal of Parts

In re Gazda, 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious expedient.).

3. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer et al. (6,522,930) in view of Kesten (6,251,104) and further in view of Berg et al. (5,680,873).

Schaer et al. (6,522,930) is silent regarding a lack of reinforcements in the polymeric material.

Berg discloses an analogous device that propounds the advantages (col. 5:9-14) of reinforcement free polymeric material in the context of the patented device such as cost.

Therefore, at the time of the invention **it would have been obvious** to one of ordinary skill in the art to modify Schaer et al. (6,522,930) in view of Kesten (6,251,104) and further in view of Berg by leaving out reinforcing material. The **motivation** would be to keep costs of manufacturing down (Berg col. 5:9-14).

Response to Arguments

Applicant's arguments filed 8-21-06 have been fully considered but they are not persuasive. The Applicant argues that no guidewire is disclosed directly corresponding to Schaer's invention in figures 14-15. However, this does not obviate the above rejections. The patent mentions in col. 25:44-45 that the invention in figures 14 and 15 is a variation of the tissue ablation assembly disclosed throughout the patent. The tissue ablation assembly disclosed in figure 1 includes a guidewire lumen (22) thereby inferring the presence of a guidewire. See corresponding disclosure in col. 12:55-61. The Office asserts that element 130 in figures 14 and 15 is directly analogous to element 16 in figure 1 **including** the guidewire lumen (22) and therefore, the invention in figures 14-15 can be read to include a guidewire notwithstanding the fact that the invention in figures 14-15 can potentially be without a guidewire. The Examiner is not simply "cobbling" "bits and pieces" from the patent, but is applying commonsensical arguments to prosecution. It's noted that the increasing complexity of the electrosurgical arts yields many patents of this type, which include numerous embodiments with different elements. It is fully appropriate to intermix different elements from different embodiments seamlessly unless doing so destroys the operation of one of the

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embodiments. Patented inventions cannot be viewed in a vacuum and most certainly different embodiments within a patent cannot be viewed in a vacuum (separate from each other). Doing so would require an inventor in a patent to disclose every element in every embodiment is every possible combination; which would yield inappropriately long disclosures. This rationale also addresses the Applicant's argument that the assembly in figure 1 has no sheath. (The embodiments in a patent are seamlessly interchangeable unless intermixing destroys an embodiment's function.) As such, the rejections are not hindsight reconstruction and are appropriately maintained.

The Applicant argues that the relevance of col. 4:20-31 is unclear. The Office asserts that regardless of the fact that the language is not directly toward the Schaer invention, **it is part of the Schaer patent**. The disclosure is relevant because it is centralized with the Schaer invention. It is part of the prior art disclosure. The fact that it is not directly related to the Schaer invention (because it is part of the background section) is wholly irrelevant. The Applicant is picking specific excerpts from the patent and viewing each excerpt in a vacuum, separate from the rest of the patent. Doing so is ineffective as the excerpts are to be read in the context of the entire patent and not solely what the Applicant defines as the boundaries of what should be considered.

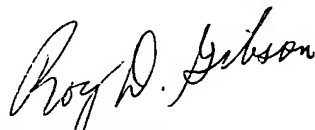
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
January 2, 2007



ROY D. GIBSON
PRIMARY EXAMINER